of the art to modify Baugh in view of Hanahan et al. and use AGEPC to gain the advantage of high platelet activation. This rejection is respectfully traversed.

As a first matter, the Examiner is reminded that Baugh and Hanahan et al. references were dealt with in a previous amendment. Specifically, in the Examiner's first Office Action, dated March 1, 2001, originally filed claims 1, 3-5, and 6-10 were rejected as being anticipated by Baugh, and claims 2 and 5 were rejected as being obvious over Baugh in view of Hanahan et al. The amendment filed May 29, 2001 in response to the first Office Action presented arguments distinguishing the pending claims over the cited art, and also added new claims 13-31, some of which were directed towards the use of a plunger sensor technique in the claimed method (see for example claims 17 and 31).

In the Examiner's final Office Action dated August 14, 2001, the Examiner stated that the amendments of May 29, 2001 had been considered by were moot in view of the new ground of rejection. The Examiner then rejected pending claims 4-6, 8 and 10-29 as being anticipated by Triplett et al. and did not state that the rejection over Baugh and/or Hanahan et al. had been maintained. In response to the final Office Action by filing an RCE, arguments were presented distinguishing the pending claims over the Triplett et al. reference, and independent claims 4, 8 and 26 were amended to incorporate the "plunger sensor technique" language from the pending dependent claims into the independent claims.

In the current Office Action, dated April 24, 2002, the Examiner appears to have withdrawn the rejection over Triplett et al. reference, and is again rejecting the claims over the Baugh and Hanahan et al. references. Thus, while it was understood that the Baugh and Hanahan et al. references had been overcome as being improper references, the remarks that were previously presented distinguishing the invention over the cited references are presented again herein.

Claim 4 is directed towards a method of determining platelet functionality and clotting characteristics of a blood sample using a plunger sensor apparatus, comprising:

> (a) dispensing an aliquot of said sample into said test cell;
> (b) adding a selected amount of a **platelet activating reagent** to said aliquot sample to form a reaction mixture;
> (c) adding a sufficient amount of a clotting reagent to said reaction mixture to promote clotting of said aliquot sample;
> (d) performing a clotting test on said aliquot sample . . . ; and
> (e) determining said platelet functionality of said sample based on the

clotting times . . ..

The platelet activating reagent enhances the ability of active platelets to effectively participate in the blood clotting reaction and thereby shorten the clotting time of the blood. If the platelets are inactive or not functioning normally, the activating reagent will have a lessened or no effect on the clotting time.

In contrast, the Baugh reference relates to an improved activated clotting time (ACT) test which accommodates the effects of platelet activation by incorporating a platelet activation phase. Baugh observed that the initial contact and interaction of the blood sample with the activating reagent affects the platelet activation, which may make the ACT test results variable and operator dependent. Baugh describes a two-phase ACT test using a plunger technique ACT test. The first phase (the platelet activation phase) comprises a predetermined time period of relatively low intensity agitation to activate the platelets in a controlled manner. Following this phase, the ACT test continues through a typical clotting test phase. Baugh states that the first phase is required in order to achieve the maximum contribution to the rate of platelet activation for an ACT and thus minimize the potential for variable results in the ACT (column 5, lines 58-63).

However, the Baugh method does not include a chemical platelet activating reagent or a clotting affecting reagent in the test cells, let alone different amounts of the platelet activating reagent to determine the platelet functionality or the clotting characteristics of the blood sample, as required by the claims of the present invention.

It is well established that the prior art relied upon must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. In addition, the prior art reference or combination of references must teach or suggest all the limitations of the claims. Without some suggestion in the cited art, there is no incentive for one of skill in the art to modify the method of the Baugh reference by adding a chemical platelet activating agent. For at least these reasons, claim 4 is not anticipated or made obvious by the Baugh reference. Claims 5-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 depend from claim 4 and therefore include all the novel and non-obvious features of claim 4. Thus for the same reasons, claims 5-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 are also novel and non-obvious in view of the Baugh reference.

Further, the fact that Hanahan *et al.* teach AGEPC as a platelet activator is irrelevant to the patentability of the present invention, since the Baugh reference provides no motivation

to one skilled in the art to modify the method of Baugh by adding a platelet activator.

For the reasons stated above, the combination of the Baugh with the Hanahan *et al.* reference does not teach or suggest the method of the present invention. Withdrawal of the Section 103(a) rejection is respectfully requested.

CONCLUSIONS

It is believed that all the claims now pending in this patent application, as amended and described above, are now allowable. Therefore, it is respectfully requested that the Examiner reconsider his rejections and to grant an early allowance. If any questions or issues remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number listed below.

It is believed that no fees are required in filing this Amendment and Remarks. However, should any fee be required, please charge Deposit Account No. 50-1123.

Respectfully submitted,

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Dated

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